Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Role of Total Motion Release in Patients with Lumbar Radiculopathy

Protocol summary

Study aim
To determine the effects of Total motion release in patients with lumbar radiculopathy functional

Design
This two arm parallel randomized trial with a sample size of 68 participants, will feature blinded assessors to evaluate outcomes related to quality of life , pain and functional disability outcome will assess

Settings and conduct
Data will be collected from Physiotherapy department in University of Lahore teaching hospital. This will be single blinded study where assessor will remain unaware of participants belong to which groups but aware of measuring outcomes.

Participants/Inclusion and exclusion criteria
Inclusion Criteria • Aged between 18-50 years • Both Male and females • Patients referred from orthopedic • Patients with positive SLR test • Having at least 5 score of Numeric Pain Rating Scale Exclusion Criteria • Patients with neurological symptoms (such as cognitive) • Patients with inflammatory disorders (rheumatoid arthritis) • Patients with specific disorders of spine (ankylosing spondylitis, severe osteoporosis, sacroiliac joint pathology) • Patients with previous spinal surgery • Current pregnancy or early postpartum period (6 months)

Intervention groups
All the screened and willing participants will be randomly allocated to two groups where Group A will receive Total motion release. This technique will be given to unaffected side thus relieving symptoms of affected side with 5 reps & 10 times. It is very simple technique in which patient is made to perform five motion they are: 1) Arm raise 2) Trunk twist 3) Leg raise 4) Sit to stand and 5) Toe reach. And group B will receive conventional Therapy. The nerve sliding technique will be applied for 20-30 repetitions in 2-3 sets per day, and the nerve tensioning technique will be implemented in addition for 15-25 seconds in 5-7 repetitions.

Main outcome variables
Pain Quality of life Functional disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240923063127N1**
Registration date: **2024-11-22, 1403/09/02**
Registration timing: **retrospective**

Last update: **2024-11-22, 1403/09/02**
Update count: **0**

Registration date
2024-11-22, 1403/09/02

Registrant information

Name
Ayesha Maroof

Name of organization / entity
University of Lahore

Country
Pakistan

Phone
+92 305 8803766

Email address
aayesha.khan12334@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-05, 1402/12/15

Expected recruitment end date
2024-10-05, 1403/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Role of Total Motion Release in Patients with Lumbar Radiculopathy

Public title
Role of Total Motion Release in Patients with Lumbar Radiculopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 18-50 years Both Male and females Patients referred from orthopedic Patients with positive SLR test Having at least 5 score of Numeric Pain Rating Scale

Exclusion criteria:
Patients with neurological symptoms (such as cognitive) Patients with inflammatory disorders (rheumatoid arthritis) Patients with specific disorders of spine (ankylosing spondylitis, paget's disease, vertebral collapse, spondylolisthesis, severe osteoporosis, Tb spine, diabetic neuropathy, stenosis, sacroiliac joint pathology) Patients with previous spinal surgery Current pregnancy or early postpartum period (6 months)

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual simple randomization will be performed by one research team member who is blinded to the study and not involved in patient recruitment. The randomization process will utilize sealed, opaque envelopes to ensure allocation concealment. The random sequence will be generated using a random number table or computer software to avoid bias. This approach ensures proper probability-based allocation and maintains the integrity of the randomization process.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single blinded study in which outcome assessor will be blinded to group allocation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Lahore

Street address
University of Lahore Teaching Hospital Lahore , Punjab , Pakistan

City
Lahore

Postal code
55150

Approval date
2024-05-09, 1403/02/20

Ethics committee reference number
REC-UOL-/163/08/24

Health conditions studied

1

Description of health condition studied
A disorder known as lumbar radiculopathy, which is characterized by irritation or compression of the nerve roots in the lumbar spine, frequently causes severe pain, functional restrictions, and a decline in quality of life.

ICD-10 code
M54.16

ICD-10 code description
Radiculopathy, lumbar region

Primary outcomes

1

Description
The pain VAS is a unidimensional measure of pain intensity, used to record patients' pain progression, or compare pain severity between patients with similar conditions.

Timepoint
Before intervention and 2nd , 4th weeks after intervention.

Method of measurement
The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health) orientated from the left (worst) to the right (best).

2

Description
The Oswestry disability Index is most sensitive for patients with mild to moderate disability due to acute, sub-acute, or chronic low back pain.

Timepoint
Before intervention and 2nd , 4th weeks after intervention.

Method of measurement

The end score is the sum of the ticked boxes. The score ranges from 0 (no disability) to 24 (max. disability) depending on the questionnaire used. Roland and Morris omitted describing the various levels of disability (for example, 40%–60% of disability is severe).

3

Description

The SF-12 is a self-reported outcome measure assessing the impact of health on an individual's everyday life. It is often used as a quality of life measure.

Timepoint

Before intervention and 2nd , 4th weeks after intervention.

Method of measurement

The SF-12 uses the exact two domains mental and physical health score as the SF-36. Patients fill out a 12-question survey which is then scored by a clinician or researcher. The score ranges from 0 (worst health) to 100 (best health) depending on the questionnaire used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants randomly will be allocated in Group A received the Total motion release. After 15 minutes of heat therapy along with TENS, neural mobilization exercises, consisting of both sliders and tensioners, will be provided. The patient will be positioned in high sitting, with the hands clasped behind and in slouched posture as base position. They will be performed neck extension and knee extension for the sliding technique, and neck flexion with knee extension for the tensioning technique . The movement range will be determined by the severity of symptoms and patient tolerance. The nerve sliding technique will be applied for 20-30 repetitions in 2-3 sets per day, and the nerve tensioning technique will be implemented in addition for 15-25 seconds in 5-7 repetitions. In total motion release treatment is given to unaffected side thus relieving symptoms of affected side with 5 reps & 10 times. It is very simple technique in which patient is made to perform five motion they are (Naik et al., 2019): 1) Arm raise 2) Trunk twist 3) Leg raise 4) Sit to stand and 5) Toe reach.

Category

Treatment - Other

2

Description

Intervention group: In Group B all allocated participants will be received conventional therapy. Conventional therapy includes 15 minutes of heat therapy along with TENS. Hot packs will be used to deliver superficial heating. Each treatment session will be lasted 30-45 minutes. TENS (Transcutaneous Electrical Nerve Stimulation) sessions will be lasted 15 min. The TENS will be applied in a conventional mode for 15 min at a high frequency of 70 Hz and wavelength of 100 microseconds by placing two 40 × 40 mm electrode sets cross arranged on each side of the lumbosacral spine.The intensity of the current will be increased to the point of observation of no contractions, but with a light tingling sensation, while ensuring the patient will be comfortable. Then mild stretches of hamstrings and piriformis muscle, core stabilization exercises and sciatic nerve mobilization will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore Teaching Hospital

Full name of responsible person

Ayesha Maroof

Street address

1-km Defence Road near Bhuptian Chowk Lahore

City

Lahore

Postal code

55150

Phone

+92 305 8803766

Email

Ayeshaa.khan1512@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Ayesha Maroof

Street address

1-km Defence Road , near Bhuptian Chowk,Lahore , Punjab

City

Lahore

Postal code

55150

Phone

+92 305 8803766

Email

Ayeshaa.Khan1512@gmail.com

Grant name

None

Grant code / Reference number

None

Is the source of funding the same sponsor organization/entity?

No

Title of funding source
none
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
University of Lahore
Full name of responsible person
Ayesha Maroof
Position
Punjab
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
1-km Defence Road , near Bhuptian Chowk,Lahore , Punjab
City
Lahore
Province
Punjab
Postal code
55150
Phone
+92 305 8803766
Email
Ayeshaa.khan1512@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Lahore
Full name of responsible person
Ayesha Maroof
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
1-km Defence Road , near Bhuptian Chowk,Lahore , Punjab
City
Lahore
Province
Punjab
Postal code
55150
Phone
+92 305 8803766
Email
Ayeshaa.khan1512@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
University of Lahore
Full name of responsible person
Ayesha Maroof
Position
Consultant
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
1-km Defence Road , near Bhuptian Chowk,Lahore , Punjab
City
Lahore
Province
Punjab
Postal code
55150
Phone
+92 305 8803766
Email
Ayeshaa.khan1512@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Demographic data and data related to final outcome will be shared by maintaining the confidentially
When the data will become available and for how long
Data will be available after the publication of findings till six months
To whom data/document is available
De-identified individual participant data (IPD) and supporting documents will be shared for research

purposes only and will be available up to six months after the publication of findings. Access is primarily for individuals working in academic institutions; however, those from other organizations, such as businesses, may also apply with a valid research proposal. Requests can be directed to the corresponding author, Ayesha Maroof, at ayeshaa.khan1512@gmail.com or +92 305 8803766. Additionally, data will be shared through public releases in accordance with established traditions for open access.

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study, Ayesha Maroof and can contact on +92 305 8803766 , Ayeshaa.khan1512@gmail.com

What processes are involved for a request to access data/document

Open access and there is the traditional public data releases where anyone can get access to the data

Comments